DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
Microvasive Endoscopy
Ms. Lisa Quaglia
Regulatory Affairs Manager
One Boston Scientific Place
Natick, MA 01760-1537

JUL 27 2015

Re: K010610
Trade/Device Name: Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC, OCY
Dated (Date on orig SE ltr): February 28, 2001
Received (Date on orig SE ltr): March 1, 2001

Dear Ms. Quaglia,

This letter corrects our substantially equivalent letter of March 27, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K010610

SECTION 1
INDICATIONS FOR USE

Device Name: Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System

Indications for Use:

The Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System consists of two accessories intended for use with Microvasive® Biliary Rapid Exchange™ devices:

The Microvasive® Rapid Exchange™ Locking Device is intended to lock the guidewire in place during ERCP procedures.

The Microvasive® Rapid Exchange™ Biopsy Cap is intended to facilitate the use of Rapid Exchange™ devices during ERCP procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091)

David A. Lagerman (Optional Format 1-2-96)
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010610

MAR 2 7 2001

K010610
Pg 1 of 2

SECTION 10
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific chooses to submit a summary of information respecting safety and effectiveness.

Date:	February 28, 2001
Common/Usual Name:	Biopsy Cap; Locking Device
Trade/Proprietary Name:	Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System
Classification Name & Device Classification:	Based on the regulatory class of the predicate devices and the information contained in FDA's classification database, Boston Scientific Corporation believes that the Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System is best described as a Class II device with the following classification names:
Name:	Endoscope and Accessories
Product Code:	KOG
21 CFR Ref.:	876.1500
Device Panel:	Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)
510(k) Sponsor & Owner/Operator:	Boston Scientific Corp. One Boston Scientific Place Natick, MA 01760-1537
Contact Person:	Lisa Quaglia, Regulatory Affairs Manager

K 100101
pg 2 of 2

Device Description:
The Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System consists of a sterile, single-patient use biopsy cap and a rigid plastic guidewire locking device for use with other Boston Scientific Rapid Exchange catheter devices.

Indications for Use:
The Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System consists of accessories intended for use with Microvasive® Biliary Rapid Exchange™ devices.

The Microvasive® Rapid Exchange™ Locking Device is intended to lock the guidewire in place during ERCP procedures.

The Microvasive® Rapid Exchange™ Biopsy Cap is intended to facilitate the use of Rapid Exchange™ devices during ERCP procedures.

Descriptive and Technological Characteristics of Proposed and Predicate Devices:
Boston Scientific Corporation believes that the Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System is substantially equivalent to other devices in the Microvasive® Rapid Exchange™ device family, including the following:

Microvasive® Extractor Rx (K970052)
Microvasive® Ultratome Rx (K970053)
Microvasive® Tandem Rx (K970054)

This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Boston Scientific has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Design Verification testing has been performed to ensure that the Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System meets design specifications.

Conclusion:
Based on the device indications for use, comparison of descriptive and technological characteristics, and design control certification, the Microvasive® Rapid Exchange™ Locking Device and Biopsy Cap System has been shown to meet the minimum requirements that are considered acceptable for its intended use.